Bentley Pharmaceuticals, Inc.

Bentley Pharmaceuticals
Project Status Report – 11 December

PROJECT AND STATUS	SCHEDULE
8. Auxillium A2 – Testosterone Current Status: Amendment signed. Status of Letter of Access to DMF? Press Release on License planned for 12/18. If McNeil visit to occur week of 12/18, then also plan for Jim to visit A2 week during same trip. - Per Bob Stote, our DMF not referenced in their IND, so no need for a letter of access to DMF. - Per Jim, press release on IND is premature at this time, however, press release on license is needed. Mike, Jordan and Bob S. working it. Need it ready for Monday 12/18. - Regulatory issues. John Cullen and Brenda Stoelzle to meet and discuss, then meet with Bob Stote - **Action:** B. Stoelzle - Call Dave Brusick to design PK animal study - **Action:** J. Murphy - PK Study for Radiolabel CPE-215 – **Action:** P. Fitzgibbons - Any work on a second amendment for CFS/FMS will be handled at later time.	31 Dec
9. Dartmouth License – CFS/FMS (Testosterone, Pregnenolone, etc) Current Status: NHIRC grant in process; proposal submitted to NHIRC on 12/7. IRB forms from Dartmouth, including protocol in process. Clinical study to commence approximately 1 April. - Two parts: a) Evaluate Testosterone in women using un-enhanced formulation gel or patch; b) Apply pregnenalone and/or other androgen (may or may not use CPE-215). - Bob and Paul participated in planning meeting at Dartmouth on 11/27. Project in full swing. Proposal submitted to NHIRC, Henry Mullaney on 12/7. - Lohmann patch issue: Out of state source of patch conflicts with FDA rules for NHIRC study. Most likely will not use patch for Dartmouth clinical study. - Mike to track as a cash related item. Note: Issue of sponsoring research on CFS/FMS discussed – waiting for call back from Judy Spence (Ministry of Health, Canada); Jim and Bob G. to talk to her at that time.	Dec '00 – Apr '01
10. Lohmann Patch Development Current Status: Potential patch development agreement with Lohmann. Strong interest in testosterone patch for FMS/CFS. - Bob and Paul visited Lohmann on 12/5 for discussion of patch development. Lohmann very interested in testosterone patch for Fibromyalgia and Chronic Fatigue. Lohmann (David Sachs) to send us a draft outline of a proposed development agreement.	Jan 01
11. Pfizer – Animal Studies (CPE 215 formulations). DONE! Current Status: Studies in animals U.S. and U.K. continuing and expanding Bob and Paul visited Pfizer on 11/20. Second batch of 8 formulations delivered. Discussion of status as well as potential vaccine use occurred. Bob provided Bentley briefing (general, transdermal, and intranasal). Following areas being tracked: - Veterinary in Sandwich, U.K.: One test completed, second test planned for Jan - Add'l programs to be started in Groton for improved solubility studies in animals (cats). - Potential use of compounds for topicals (acne work). - Preparing 8 new formulations for 12/20 delivery to Warner-Lambert in Ann Arbor, MI for study in pigs.	Nov/Dec

Bentley Pharmaceuticals
Project Status Report – 11 December

PROJECT AND STATUS	SCHEDULE
12. Italpharmaco (Portugal) – Omeprazole and Enalapril Current Status: Out-Licensing issue. Review out-licensing document – Action: J. Horvath. **On hold, pending results of Ethypharm.**	On Hold
13. Helm AG – Omeprazole Current Status: Jim/Jordan contract issue for out-licensing. Review out-licensing document – Action: J. Horvath. **On hold, pending results of Ethypharm.**	On Hold
14. Teva – Generics Current Status: Need to know results of due diligence review of Omeprazole patent. Review docs due back from Teva on 12/14. Potential regulatory approval for first 13 new generics - Teva to perform due diligence review of Omeprazole patents prior to European use. Per phonecon Mike and Adolfo, review documents expected back from Teva on 12/14.	Dec
15. UNH – GnRH Current Status: Discussions with Stacia Sower continuing. Agreement is now being modified for use of mice instead of lamprey eels. **12/11 mtg: No update provided.**	
16. Knoll Pain Mgt - Insulin, diclofenac gel, oxycodone nasal, hydrocodone nasal Invited us for pain management brainstorming session in New Jersey end of Nov (Gyurik, Stote, Murphy). Concentration will be on diclofenac. **12/11 mtg: No update provided.**	
17. Boston Life Sciences Current Status: Jim to find point of contact and send email. Three areas of interest: intranasal, triponem, inosein. **12/11 mtg: No update provided.**	
18. Radiolabel CPE-215 Current Status: Meeting held with NEN on 11/15. Quotes received for costs of various labeling. Separate quote for tritium labeling obtained. Need to decide whether to proceed or not with radiolabeling. - Investigate potential radiolabeling of CPE-215with New England Nuclear (NEN), Amersham and ICN. **Action:** P. Fitzgibbons and Bob Gyurik. - Meeting held with NEN on 11/15. Quotes received for costs of various labeling. Separate quote for tritium labeling obtained. (also had separate visit from Calvert Pre-clinical, Worcester, MA. They can perform radiolabel tests as well (in rats)). - Holding off on contact with Amersham and ICN, pending need to proceed with radiolabeling and potential engagement of NEN. **Action:** P. Fitzgibbons and Bob Gyurik	31 Dec
19. GlaxoSmithKline Current Status: Meeting with GlaxoSmithKline attended by Adolfo in U.K. Results good. Follow-on meeting planned for 1/15/01 in Madrid. SmithKline wants to market throughout Europe and 16 other Pacific nations. Need to get list of nations.	15 Jan
20. Bertek - Current Status: On-going evaluations. 11/9 mtg - Per Bob G. nothing expected here for four months.	Feb

Bentley Pharmaceuticals
Project Status Report – 11 December

PROJECT AND STATUS	SCHEDULE
21. Duke- Vaccines Current Status: MTA draft under review. Jordan contacted Duke 12/11, relationship in question. Follow-up by Jim/Bob G. required. - Consulting agreement drafted. Revised MTA forwarded on 11/3, pending response – Action: J. Horvath. Jordan working on third set of comments. - Jordan contacted Duke on 12/11. Relationship appears to be in question. **Follow up by Jim and Bob G. required. Action: J. Murphy and Bob G.**	Jan
22. Path Tox (Nail Lacquer) – FDA Review Current Status: Need to talk to Fred Reno or other advocate to clarify that CPE-215 is not same as angelica lactone cited in FDA reviewer's sheet. Need to pull from FDA report items supporting our case for CPE-215. **12/11 mtg: Not discussed.** Path – Tox. (FDA meeting) – Nail Lacquer. Discussed Fred Reno letter regarding FDA reviewer's report. Need to clarify to Fred that CPE-215 (cyclopentadeca- lactone or cyclopentadecanolide) is not the same as angelica lactone (confusion exists in literature) – **Action:** B. Gyurik. Obtain full report from FDA report, Scientific Literature Review of Aliphatic Lactones in Flavor Usage, and glean supportive info from it – **Action:** B. Gyurik. Actions essential to prevent unnecessary complete path tox studies (Irritation, Mutagenicity, Seg II Teratology) 11/14 mtg – Review of FDA report (lengthy) in progress.	31 Dec
23. Merck Current Status: Jim to check with Christianson. **12/11 mtg: Not discussed.**	31 Dec
24. Amgen – Peptides Current Status: Need to find point of contact and follow-up on contact. **Action**: B. Gyurik or J. Murphy. **12/11 mtg: Not discussed.**	31 Dec
25. Ethypharm Current Status: Ethypharm will send us licensing contract 3rd week of December. Bottom line – deal will not be completed this calendar year.	Jan
26. New Patents - Europe Current Status: Need status of foreign patent filings: Omeprazole, Acetaminophen, provisionals (oral, nasal, lacquer). Is Ungria handling these? - Call Adolfo to discuss need for assistance on foreign patent filings for Omeprazole, Acetaminophen, etc. **Action:** P. Fitzgibbons. a) Paracetamol (Acetaminophen) Current Status: - Patent translated and re-worked from Spanish to English (Ivo, Paul and Bob). - Patent attorneys reviewed on 10/30. Press release issued on 11/6. Bob Gyurik to call patent attorney (Eliot Olstein) to commence review. **Action**: B. Gyurik - Patent signed. Promotion of new patent needed. Call McNeil, Pharmacia UpJohn and Wyeth Jim contacted McNeil and Spain. Samples provided. - SmithKline expressed strong interest in using world-wide (see GlaxoSmithKline) b) Omeprazole Patent Current Status: Date of release to be determined after 11/22 meeting with Ethypharm. Bob Gyurik to call patent attorney (Eliot Olstein) to commence review.	Dec

Bentley Pharmaceuticals, Inc.

Bentley Pharmaceuticals
Project Status Report – 11 December

PROJECT AND STATUS	SCHEDULE
29. Strategic Committee Meetings Current Status: Strategic Committee Meetings to be held in concurrence with BOD in January. Jordan to be here 9 Jan to work on in house review. Revised schedule below: Plan and action dates as follows: - 12/11/00 – draft documents completed? - 1/08/01 – review documents in house - 1/15/01 – documents to BOD - 1/28/01 – discuss at Board Meeting	Dec/Jan
30. Investment Banking Current Status: Need to obtain platform for launch of U.S. products (e.g., Mission Pharmacal). Offer to handle from Dain Rausch involves unacceptable upfront costs plus more. Mike and Jordan to look elsewhere. General info: Need U.S platform for launch of U.S. products. Figure $75M for acquisition. Pay in stock plus "earnout": Issue warrants to vest in 60 days. ($30M in stock, plus mid-point of stock in 60 days). Need to raise our market cap to approx $250M and identify potential takeover candidate (Need candidate, preferably before BOD meeting in January.) - Mike informed by Dain Rausch, Ed L., that they want excessive upfront funds to handle any m&a for us. Mike to respond that there are others of equal or larger size who are willing to work with us without upfront costs. - Discussed near term expiring warrants and whether to extend or not. Ideally need a securities firm to write good research report which in turn would encourage exercise of warrants, however, a report is not likely prior to having good news of a potential market cap increase through takeover or merger. **Action: Decision on warrants needed by mid January prior to BOD meeting.** - Mike and Jordan to investigate other investment banking sources: AmeriCal Securities, Credit Suisse First Boston (Dave Maris, Ann Friedrich), First Security Van Kasper, and Brean Murray).	Jan
31. Mission Pharmacal Company, San Antonio, TX Current Status: Response from Dain Rausch unacceptable. - Plan/schedule intro/visit and product review within 30 days – Action: J. Murphy and B. Stote. - Mike contacted Dain Rausch, Ed L. They want $200K upfront, plus royalties for M&A work . Mike to respond that there are others of equal or larger size who are willing to work with us.	Jan
32. Investor Relations: Porter, LeVay and Rose Current Status: Issues – Investor Relations Plan for Yr 2001? Add PLR as contact on Bentley web site, reduce scope of PLR to press releases only? - Mike to talk to PLR regarding Investor Relations plan for Year 2001 - Mike to look at feasibility of auto-download of Investor Relations documents (pdf files) from Bentley web site.	31 Dec
33. Electronic Promotion Current Status: Electronic Licensing web sites under review by Paul. Review electronic licensing companies/web sites for potential Bentley use, placement of press releases, etc. **Action:** P. Fitzgibbons. - Paul contacted PLA (Linda Decker) and provided points of contact for Pharma Company Insight and QX Health Newswire (Datamonitor). They should run our press releases in future. - Others to look at: Licensing Executives Society (LES) and Pharmquest 3D.	Continuing

12/18/00 ADOLFO

OMEPRAZ

ANTIBIOTICOS - Supply for

Mexico	525	28 CAP
Costa Rica	322	14 CAP
Peru	480	BULK
Honduras		
Guatemala		

SKB - Ltr. still due this week

TEVA - Power of Attorney

CALL @ 11:00

Ethypharm

Negotiate New Price - WEDNESDAY

LeDuc in Taipei

Awaiting New Agreement

Paracetamol

12/19 JORDAN

VAN KASPER

1st Boston / DLJ

12/18 ARNIE COGL ASSOCIATES

WARBURG PINKUS - 5 Billion Fund

12/18 Michael Craig - VAN KASPER 408 947-3850

B400

12/19 Joe Sondel

Joe Has
600K wts
Peter
180K wts
M. Bakal
wts
M. McGovern
2800 wts

3,580 of 5.55

- EXTENDING

12/20 Bill Quinn - Prefers an extension wts.

12/20 Spain

Ethypharm prices SIGN TOMMORROW
TEVA - Spanish Lawyer
SHIRE - 2nd Payment of TAXES 75mil pstas.
50% price + 50% TAXES - in PAST
D&T - all
Translar - w/in 60days - Feb
TEVA - omprezole - decision in Jan

-502058-

B401

12/19/00 PEGASUS

Dr. Robert Zerbe CEO
Dr. Stuart Dombey CSO
mr. Chris Nicolas VP Corp Dev.

- Partner w/ others to advanced stage
- Shared $ Risk - Reward

* Diclofenac — Diclofenac? Insulin

* Insulin Venture — "Innovators Dilema"

Thru PH. II
$ & Expertise - ownership

Intranasal Pain Mangement

Formulation

12/20 Ethypharm France

Labuc's ASSISTANT - Contract will be ready Friday

Bentley Pharmaceuticals, Inc.

Bentley Pharmaceuticals
Project Status Report – December 20, 2000

PROJECT AND STATUS	SCHEDULE
1. Shire USA – Oral R&D Licensing Collaboration Current Status: - Draft contract in process. Pending response to comments from Khatar on 12/20. - Bob G. to call Synnestvedt & Lechner to commence review. Bob G. sent Record of Invention on 12/20 to start the process. **Action:** B. Gyurik. - Provisional almost complete. Text of claim almost completed. Complete in Jan.	Jan
2. Shire Europe – Product Sale (Controlvas) Current Status: - Product sale completed. PR issued 11/28. Pending approval by Ministry of Health. - Additional 75M pesetas for the IVA. Balance of purchase price due within 60 days (15 Feb).	28 Nov
3. Alcon – Ocular Current Status: - Agreement signed 12/20. Jordan sent final MTA to them on 12/20. - Per conference call 12/20; screening to confirm no irritation, etc. - Need to hold planning session with them and discuss/determine what formulations to send. **Action: B. Gyurik.**	Dec/Jan
4. Onychomycosis – Nail Lacquer Current Status: a) Schering Plough - Committee to meet again first week of Jan with decision expected by 16 Jan. - S-P has concerns over Penlac, Dimethaid and Macrochem. Jordan forwarded right of first refusal agreement on 10/31. b). Toenail Study – Interested McNeil, Wyeth, Pfizer – - McNeil – Jim and Bob G. visited McNeil in Valley Forge, PA week of Oct 23rd. Two meetings planned: one on paracetamol and another with Pete Dadonka. Problems with clearing customs. Jordan to investigate getting customs agent. **Action: Jordan** - Wyeth – asked for a product profile on nail lacquer. Need to schedule a presentation for them at Wyeth within 30 days - **Action:** B. Gyurik and J. Murphy. Jim to send Wyeth/Whitehall the press release on paracetamol – **Action:** J. Murphy. - Pfizer – Jim to talk to Keith about their potential interest in our nail lacquer. Jim sent product profile info to Keith on 11/10. No word received yet. Note: Potential visit to McNeil and Wyeth (and Auxillium) week of 12/25.	Dec
5. UAB Nail Lacquer Clinical Study Current Status: - IRB approval of protocol for additional toenail study still pending. - Planning for new batches of lacquer in early Jan (for toenails, plus more for finger nails) - Assembly and shipping of patient kits by mid Jan. Bob G. to resolve nail file issue (metal or other) – **Action: B. Gyurik.**	Jan
6. Bristol-Myers Squibb – Nail Lacquer (add'l clinical) Current Status: - Two evaluations by BMS: 14 Nov and another in Feb. Jim to call Joe Loftus in February to discuss results. **Action: J. Murphy.** - Need to schedule a meeting at Princeton after contact to discuss technology; transfer - **Action:** B. Gyurik, P. Fitzgibbons and I. Velazco	Feb

Bentley Pharmaceuticals, Inc.

Bentley Pharmaceuticals
Project Status Report – December 20, 2000

PROJECT AND STATUS	SCHEDULE
Note: Jim contacted Ron McCrae 11/14. Jim sending info (all our capabilities specific to pain mgmt) to them on 11/14. Need Jim/Bob to work on intranasal products profile – **Action:** J. Murphy and B. Gyurik. Need to call Ron McCrae again week of 12/18. **Action: J. Murphy**	
7. Insulin – Development Issues Current Status: a) Supply – Sources. Obtain a contingency supply of insulin. - Various organizations including Bachem being looked at for potential supply. - **Taipei, Taiwan:** Jim and Bob G. had productive visit to Taipei week of 11 Dec. Need to follow up with letters to various contacts in Taipei. **Action: J. Murphy** - **Pegasus:** Meeting held on 19 Dec with Dr. Zerbe, et al. Jordan to send Confidentiality Agreement to Pegasus by 22 Dec. **Action: J. Horvath.** Expect Pegasus to follow-up first week of Jan with Term Sheet. - **India:** Jim to discuss with Mike McGovern and then call Atul. **Action: J. Murphy.** Eventual Visit to Bombay, India to visit Sarabhai Piramal to negotiate supply and inspect for GMP compliance (certificate needed, DMF?). Need list of various forms of insulin manufactured at India facility for intranasal use. They confirmed manufacturing capability with Sarabhai Piramal. [Atul Parvatiyar: 770-931-8821 (H); 678-427-1679 (cell); 404-327-9100 (office)] **Note:** Mike to track insulin development as a cost related issue. b) Regulatory **(to be discussed after supplier selected)** 1) Pre-Clinical: 11/9 mtg – Deferred. - Talk to Roger Wells - Action: B. Gyurik - Brenda, Bob S. and Bob G., Fred Reno – For planning 2) Clinical: - Enlist support of Sherwyn Schwartz . 11/9 mtg – Schwartz is willing to test but not be involved with development. Action: B. Gyurik. - Enlist support of Dartmouth Medical. 3) CMC: c) Formulation/Development **(to be discussed after supplier selected)** - Call Mayron. Mayron needs to start at square one. This issue deferred until after meeting with Yvon Durant on 10/31. 11/9 mtg – Further delayed - Action: B. Stote - Call UWVa for formulation assistance - Action: J. Murphy - Meet with Yvon Durant on Tuesday, 10/31 to discuss intranasal insulin - **Action:** B. Stote, B. Gyurik, J. Murphy, P. Fitzgibbons. 11/9 mtg – Meeting with Yvon completed on 10/31. Formulation will take time.	31 Dec
8. Auxillium A2 – Testosterone Current Status: - Amendment signed. Press Release on License was issued on 18 Dec. If McNeil visit to occur week of 12/25, then also plan for Jim to visit Auxillium during same trip. - Per Bob Stote our DMF not referenced in Auxillium IND, therefore, a letter of access is not required. - Regulatory issues. John Cullen and Brenda Stoelzle to meet and discuss, then meet with Bob Stote - **Action:** B. Stoelzle	31 Dec

Bentley Pharmaceuticals, Inc.

Bentley Pharmaceuticals
Project Status Report – December 20, 2000

PROJECT AND STATUS	SCHEDULE
9. Dartmouth-Bentley NHIRC Grant – FMS/CFS (Testosterone, Pregnenolone, DHEA) Current Status: - Grant proposal submitted to NHIRC, Henry Mullaney, on 12/7. Waiting for response. .IRB forms from Dartmouth, including protocol in process. More progress expected after holidays in early Jan. Clinical study to commence approximately 1 April. - Mike to track as a cash related item. Note: Issue of sponsoring research on CFS/FMS discussed – waiting for call back from Judy Spence (Ministry of Health, Canada); Jim and Bob G. to talk to her at that time.	Dec '00 – Apr '01
10. Lohmann Patch Development Current Status: - Potential patch development agreement with Lohmann. Strong interest in testosterone patch for FMS/CFS. - Bob and Paul visited Lohmann on 12/5 for discussion of patch development. Lohmann very interested in testosterone patch for Fibromyalgia and Chronic Fatigue. Lohmann (David Sacks) to send us an outline of a proposed development agreement. Follow-up after holidays.	Jan 01
11. Pfizer – Animal Studies (CPE 215 formulations). DONE! Current Status: Studies in animals U.S. and U.K. continuing and expanding. Bob and Paul visited Pfizer on 11/20. Second batch of 8 formulations delivered. Discussion of status as well as potential vaccine use occurred. Following areas being tracked: - Veterinary in Sandwich, U.K.: One test completed, second test planned for Jan - Add'l programs to be started in Groton for improved solubility studies in animals (cats). - Potential use of compounds for topicals (acne work). - Preparing 8 new formulations for 20 Dec delivery to Warner-Lambert in Ann Arbor, MI for study in pigs.	Nov/Dec
12. Italpharmaco (Portugal) – Omeprazole and Enalapril Current Status: Out-Licensing issue. Review out-licensing document – Action: J. Horvath. **On hold, pending results of Ethypharm.**	On Hold
13. Helm AG – Omeprazole Current Status: Jim/Jordan contract issue for out-licensing. Review out-licensing document – Action: J. Horvath. **On hold, pending results of Ethypharm.**	On Hold
14. Teva – Generics Current Status: Need to know results of due diligence review of Omeprazole patent. Review docs due back from Teva on 12/14. Potential regulatory approval for first 13 new generics - Teva to perform due diligence review of Omeprazole patents prior to European use. Per phonecon Mike and Adolfo, review documents expected back from Teva on 12/14.	Dec
15. UNH – GnRH Current Status: Grant expected to be declined, because of excessive number being granted for Bentley. Plan to resubmit at later date.	On Hold

Bentley Pharmaceuticals, Inc.

Bentley Pharmaceuticals
Project Status Report – December 20, 2000

PROJECT AND STATUS	SCHEDULE
16. Knoll Pain Mgt - Insulin, diclofenac gel, oxycodone nasal, hydrocodone nasal Current Status: Invited us for pain management brainstorming session in New Jersey end of Nov (Gyurik, Stote, Murphy). Concentration will be on diclofenac. **Knoll has been bought by Abbott. Wait until dust settles to proceed further.**	Jan
17. Boston Life Sciences Current Status: Jim to find point of contact and send email. Three areas of interest: intranasal, triponem, inosein. **12/20 mtg: No update provided.**	
18. Radiolabeling of CPE-215 Current Status: - Meeting held with NEN on 11/15. Quotes received for costs of various labeling. Separate quote for tritium labeling obtained. (also had separate visit from Calvert Pre-clinical, Worcester, MA. They can perform radiolabel tests as well (in rats)). - Call Dave Brusick to design PK animal study - **Action:** J. Murphy	31 Dec
19. GlaxoSmithKline Current Status: Meeting with GlaxoSmithKline attended by Adolfo in U.K. Results good. Follow-on meeting planned for third week of Jan in Madrid. SmithKline wants to market throughout Europe and 16 other Pacific nations. Need to get list of nations.	19 Jan
20. Bertek - Current Status: On-going evaluations. 11/9 mtg - Per Bob G. nothing expected here for four months.	Feb
21. Duke- Vaccines Current Status: - Jim discussed with Herman Staats and confirmed they still desire to pursue the effort. Jordan to re-work the MTA and Jim to send direct to Herman Staats (by-pass the "TBCs") – **Action: J. Horvath and J. Murphy.** - Need to send formulations to Herman in 3-4 weeks. **Action: B. Gyurik**	Jan
22. Path Tox (Nail Lacquer) – FDA Review Current Status: 12/20 mtg. - Jim discussed with Fred Reno, and provided urinalysis, hematology, and clinical data to amend the report. Issue: Path – Tox. (FDA meeting) – Nail Lacquer. Discussed Fred Reno letter regarding FDA reviewer's report. Need to clarify to Fred that CPE-215 (cyclopentadeca- lactone or cyclopentadecanolide) is not the same as angelica lactone (confusion exists in literature). Obtain full report from FDA report, Scientific Literature Review of Aliphatic Lactones in Flavor Usage, and glean supportive info from it. Essential to prevent unnecessary complete path tox studies (Irritation, Mutagenicity, Seg II Teratology)	31 Dec
23. Merck Current Status: Jim confirmed that they have interest in CPE-215. Jim to check with Christianson. **Action: J. Murphy.**	31 Dec
24. Amgen – Peptides Current Status: Jim provided point of contact: Dr. Bruce Burton. Phone 805-447-1837. Need to contact him - **Action: B. Gyurik or J. Murphy.**	Jan

Bentley Pharmaceuticals, Inc.

Bentley Pharmaceuticals
Project Status Report – December 20, 2000

PROJECT AND STATUS	SCHEDULE
25. Ethypharm Current Status: Contract to be received from Ethypharm by 22 Dec. Jordan to review – **Action: J. Horvath;**	Jan
26. New Patents - Europe General: Need status of foreign patent filings: Omeprazole, Acetaminophen, provisionals (oral, nasal, lacquer). Is Ungria handling these? - Need to discuss with Adolfo if assistance needed on foreign patent filings for Omeprazole, Acetaminophen, etc. **Action: J. Murphy and P. Fitzgibbons.** - Need to identify various patent attorney firms, evaluate and select best one to assist us – **Action: J. Horvath.** a) Paracetamol (Acetaminophen) Current Status: - Patent translated and re-worked from Spanish to English (Ivo, Paul and Bob). - Patent attorneys reviewed on 10/30. Press release issued on 11/6. Need to call Synnestvedt & Lechner to commence review. **Action: B. Gyurik** - Patent signed. Promotion of new patent needed. Call McNeil, Pharmacia UpJohn and Wyeth Jim contacted McNeil and Spain. Samples provided. - SmithKline expressed strong interest in using world-wide (see GlaxoSmithKline) b) Omeprazole Patent Current Status: - Date of release to be determined after 11/22 meeting with Ethypharm. - Need to call Synnestvedt & Lechner to commence review – Action: B. Gyurik.	Dec
29. Strategic Committee Meetings Current Status: Strategic Committee Meetings to be held in concurrence with BOD in January. Jordan to be here 9 Jan to work on in house review. Revised schedule below: Plan and action dates as follows: - 1/08/01 – complete draft documents - 1/08/01 (week of) – review documents in house - 1/15/01 – documents to BOD - 1/28/01 – discuss at Board Meeting	Jan
30. Investment Banking Current Status: Need to obtain platform for launch of U.S. products, plus increase market cap. Need U.S platform for launch of U.S. products. Figure $75M for acquisition. Pay in stock plus "earnout": Issue warrants to vest in 60 days. ($30M in stock, plus mid-point of stock in 60 days). Need to raise our market cap to approx $250M and identify potential takeover candidate (Need candidate, preferably before BOD meeting in January.) - Mike informed by Dain Rausch, Ed L., that they want excessive upfront funds to handle any M&A for us. Mike to respond that there are others of equal or larger size who are willing to work with us without upfront costs. - Mike and Jordan to investigate other investment banking sources: AmeriCal Securities, Credit Suisse First Boston (Dave Maris, Ann Friedrich), First Security Van Kasper, and Brean Murray).	Jan

Bentley Pharmaceuticals, Inc.

Bentley Pharmaceuticals
Project Status Report – December 20, 2000

PROJECT AND STATUS	SCHEDULE
31. Potential Mergers & Acquisitions a) Mission Pharmacal Company, San Antonio, TX - Potential visit by Jim and Bob Stote. b) Chatham (Tennessee) - Meeting scheduled by Jim with Scott Probosco.	Jan
32. Investor Relations: Porter, LeVay and Rose Current Status: Issues – Investor Relations Plan for Yr 2001? Add PLR as contact on Bentley web site, reduce scope of PLR to press releases only? - Mike to talk to PLR regarding Investor Relations plan for Year 2001 - Mike to look at feasibility of auto-download of Investor Relations documents (pdf files) from Bentley web site.	31 Dec
33. Electronic Promotion Current Status: Electronic Licensing web sites under review by Paul. Review electronic licensing companies/web sites for potential Bentley use, placement of press releases, etc. **Action:** P. Fitzgibbons. - Paul contacted PLA (Linda Decker) and provided points of contact for Pharma Company Insight and QX Health Newswire (Datamonitor). They should run our press releases in future. - Others to look at: Licensing Executives Society (LES) and Pharmquest 3D. - PharmaVentures.	Continuing

From: Paul Fitzgibbons
Sent: Wed, 27 Dec 2000 15:36:57 GMT
To: 'Bolling Charles (Chic) (E-mail)'; 'Cleveland Russell (E-mail)'; 'Fernandez Miguel (E-mail)'; 'Gyurik Bob (E-mail)'; 'Murphy Jim (E-mail)'; Mike Price; 'Packer William (E-mail)'; 'Stote Bob (E-mail)'; 'McGovern Mike (E-mail)'; Jordan Horvath
CC:
BCC:
Subject: Bentley Pharmaceuticals Operations Update

Below is the Bentley Pharmaceuticals Operations Update for December. The update contains highlights of our activities as discussed at our operations/staff meetings. The update is organized into three areas: Spain Activities, Product Development, and US Licensing Activities. Suggestions are welcome. Please contact Jim directly if you have questions related to any specific activity.

1. Spain Activities

a. Sale of Controlvas (branded version of Enalapril) to Shire - product sale completed 21 Nov with press release issued on 28 Nov. Final payment due arround 15 Feb.

b. Filed new patent on Paracetamol (Acetaminophen) - press release issued 6 Nov. Pursuing world-wide patent filings through Ungria.

c. Received approval to market generic Omeprazole in Spain - press release issued 10 Nov.

d. Pursuing world-wide patents for new Omeprazole and other gastric sensistive drugs.

e. Ethypharm desires Bentley take over their industrial business. Receipt of Ethypharm contract expected last week of December. Deal may possibly be completed early in Jan 2001.

f. Teva - reviewing Omeprazole for other European use. Teva has also expressed interest in our nail lacquer. A meeting with Teva is planned to be held in Philadelphia in the near future. Another meeting in Feb in Europe is also planned.

2. Product Development

a. Onychomycosis (Nail Lacquer) - Amendment of existing protocol to extend Phase I for 90 days has been submitted. Also submitted a new protocol for expansion of the UAB nail lacquer clinicals to include toenails. Both protocols are under review by the IRB. Toenail clinicals expected to start in Jan at UAB.

b. Intranasal Insulin - Continuing search for source of insulin supply. Visited Taipei in December. Several promising possibilities. Also investigating a company in Bombay, India as another potential source (meeting scheduled for 24 Jan).

c. Auxilium A2 - press release issued 18 Dec announcing license agreement with Auxilium for a topical testosterone gel using CPE-215. Auxilium has filed an IND. FDA approval as of 22 Dec.

d. Dartmouth - Obtained patent license for treatment of Fibromyalgia and Chronic Fatigue Syndrome using testosterone, pregnenolone, and DHEA - press release was issued 1 Nov. A New Hampshire IRC grant has been submitted with approval anticipated in early January. Clinical studies would start approximately 1 April at the Dartmouth-Hitchcock Medical Center.

e. Duke University - Testing of vaccines intranasally in animals (mice). The MTA is being re-worked. Interest

from Duke is still strong. Testing scheduled in Feb.

f. Two UNH Grant Studies continuing - 1) formulation studies for nail lacquer, intranasal spray; and 2) hormone gels and intranasal spray testing in animals.

3. US Licensing Activities

a. GlaxoSmithKline - has indicated strong interest in potential worldwide use of Paracetamol. GlaxoSmithKline desires to market throughout Europe and 16 other Pacific nations. Based on 10-11 Dec meeting in London, the potential for a licensing agreement is excellent. A follow-up meeting will be held in Madrid the 3rd week of Jan.

b. Schering-Plough - interest in our nail lacquer is still strong, however, the Schering committee is proceeding cautiously and slowly. Committee will meet again the first week of Jan with a decision anticipated by 16 Jan. Schering has also expressed interest in CPE-215 for planters wart use. Follow-up in progress.

c. McNeil - expressed interest in nail lacquer and also Paracetamol. Samples and copy of patent provided to them. Visit planned soon.

d. Shire USA - Oral drug development collaboration. The MTA is in process. Anticipate completion of the provisional patent by early January.

e. Pfizer - four studies in process: 1) veterinary in U.K.; 2) solubility studies in animals - Groton, CT; 3) eight new compounds for animal studies (pigs) at Warner-Lambert in Ann Arbor, MI.; and 4) potential use of compounds for topicals (acne). Pfizer reported success with the initial evaluation in the UK. We provided information on the patents, cost, manufacturing, and DMF. The eight new formulations delivered in Nov were re-directed for use in Ann Arbor, MI. Pfizer has made multiple payments to Bentley.

f. Pfizer USA - has invited us to participate in vaccine studies. Meeting was held 20 Nov in Groton, CT to discuss potential for future development (may or may not happen). Pending report back from Pfizer.

g. Alcon - the MTA was signed 20 December. Conference call with them planned for last week of Dec. We are proposing that Alcon conduct screening for irritation in the eye. Thereafter, we need to hold planning session with them to discuss formulations.

Paul Fitzgibbons
Director of Special Projects
Bentley Pharmaceuticals, Inc.
603-964-8006 (office) 603-964-6889 (fax)
pfitzgibbons@bentleypharm.com

From: Paul Fitzgibbons
Sent: Wednesday, December 27, 2000 11:37 AM
To: 'Bolling Charles (Chic) (E-mail)'; 'Cleveland Russell (E-mail)'; 'Fernandez Miguel (E-mail)'; 'Gyurik Bob (E-mail)'; Jim Murphy; Mike Price; 'Packer William (E-mail)'; 'Stote Bob (E-mail)'; 'McGovern Mike (E-mail)'; Jordan Horvath
Subject: Bentley Pharmaceuticals Operations Update

Sensitivity: Confidential

Below is the Bentley Pharmaceuticals Operations Update for December. The update contains highlights of our activities as discussed at our operations/staff meetings. The update is organized into three areas: Spain Activities, Product Development, and US Licensing Activities. Suggestions are welcome. Please contact Jim directly if you have questions related to any specific activity.

1. Spain Activities

a. Sale of Controlvas (branded version of Enalapril) to Shire - product sale completed 21 Nov with press release issued on 28 Nov. Final payment due arround 15 Feb.

b. Filed new patent on Paracetamol (Acetaminophen) - press release issued 6 Nov. Pursuing world-wide patent filings through Ungria.

c. Received approval to market generic Omeprazole in Spain - press release issued 10 Nov.

d. Pursuing world-wide patents for new Omeprazole and other gastric sensistive drugs.

e. Ethypharm desires Bentley take over their industrial business. Receipt of Ethypharm contract expected last week of December. Deal may possibly be completed early in Jan 2001.

f. Teva - reviewing Omeprazole for other European use. Teva has also expressed interest in our nail lacquer. A meeting with Teva is planned to be held in Philadelphia in the near future. Another meeting in Feb in Europe is also planned.

2. Product Development

a. Onychomycosis (Nail Lacquer) - Amendment of existing protocol to extend Phase I for 90 days has been submitted. Also submitted a new protocol for expansion of the UAB nail lacquer clinicals to include toenails. Both protocols are under review by the IRB. Toenail clinicals expected to start in Jan at UAB.

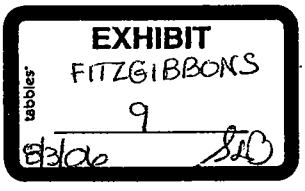
b. Intranasal Insulin - Continuing search for source of insulin supply. Visited Taipei in December. Several promising possibilities. Also investigating a company in Bombay, India as another potential source (meeting scheduled for 24 Jan).

c. Auxilium A2 - press release issued 18 Dec announcing license agreement with Auxilium for a topical testosterone gel using CPE-215. Auxilium has filed an IND. FDA approval as of 22 Dec.

d. Dartmouth - Obtained patent license for treatment of Fibromyalgia and Chronic Fatigue Syndrome using testosterone, pregnenolone, and DHEA - press release was issued 1 Nov. A New Hampshire IRC grant has been submitted with approval anticipated in early January. Clinical studies would start approximately 1 April at the Dartmouth-Hitchcock Medical Center.

e. Duke University - Testing of vaccines intranasally in animals (mice). The MTA is being re-worked. Interest from Duke is still strong. Testing scheduled in Feb.

f. Two UNH Grant Studies continuing - 1) formulation studies for nail lacquer, intranasal spray; and



2) hormone gels and intranasal spray testing in animals.

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Paul Fitzgibbons
Director of Special Projects
Bentley Pharmaceuticals, Inc.
603-964-8006 (office) 603-964-6889 (fax)
pfitzgibbons@bentleypharm.com

12/ Mike Bread

4 Gp.
- Trinity Gp - 40K,
- SKaggs
-

50-60K shares

12/28/00 SPAIN

Omprezole
Capacity Now 8 batches/mo w/2 shifts
NEED 10-11 Batches/mo
w/ 4Qwifn
2002-03 patent expire for omprezole
* Our manuf. process
1400 psts. Ethy Scles 8 mil. USD
400 mil. profit 2.3 mil USD
Ellrand
Eubrand - Italy
Osmopharm - Switz

B413

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CONFORMED PERIOD OF REPORT:     20011231
FILED AS OF DATE:               20020215

FILER:

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                CENTRAL INDEX KEY:                      0000821616
                STANDARD INDUSTRIAL CLASSIFICATION:     PHARMACEUTICAL PREPARATIONS [2834]
                IRS NUMBER:                             591513162
                STATE OF INCORPORATION:                 DE
                FISCAL YEAR END:                        1231

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                SEC FILE NUMBER:        001-10581
                FILM NUMBER:            02552283

        BUSINESS ADDRESS:
                STREET 1:               65 LAFAYETTE RD  3RD FLR
                CITY:                   NORTH HAMPTON
                STATE:                  NH
                ZIP:                    03862
                BUSINESS PHONE:         6039648006

        MAIL ADDRESS:
                STREET 1:               65 LAFAYETTE RD 3RD FLR
                CITY:                   NORTH HAMPTON
                STATE:                  NH
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EXHIBIT
M. Pierce
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7/25/06
tabbies

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

X — ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the fiscal year ended DECEMBER 31, 2001

OR

— TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the transition period from ---------- to ----------

B414

Commission File Number 1-10581

BENTLEY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	No. 59-1513162
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification no.)
65 Lafayette Road, 3rd Floor, North Hampton, NH	03862
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (603) 964-8006

Securities registered pursuant to section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $.02 par value	American Stock Exchange and Pacific Exchange
Class B Redeemable Warrants	American Stock Exchange

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES X NO

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

State the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant. The aggregate market value shall be computed by reference to the price at which the common equity was sold, or the average bid and asked prices of such common equity, as of a specified date within 60 days prior to the date of filing.

Title of Class	Aggregate Market Value	As of Close of Business on
Common Stock, $.02 par value	$132,379,932	February 8, 2002

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

Title of Class	Shares Outstanding	As of Close of Business on
Common Stock, $.02 par value	14,597,400	February 8, 2002

DOCUMENTS INCORPORATED BY REFERENCE

Proxy Statement for the 2002 Annual Meeting of Stockholders (Incorporated by Reference into Part III of this Form 10-K

<PAGE>

PART I

ITEM 1. BUSINESS

OVERVIEW

We are a specialty pharmaceutical company focused on advanced drug delivery technologies and pharmaceutical products. We have U.S. and international patent and other proprietary rights to technologies that enhance or facilitate the absorption of drugs across membranes of the skin, mouth, nose, vagina and eye. We are developing products incorporating these technologies and seek to form strategic alliances with major pharmaceutical and biotechnology companies to facilitate the development and commercialization of our products. We currently have strategic alliances regarding our drug delivery technologies with Pfizer Inc and Auxilium A2, Inc. and are in preliminary discussions with a number of other pharmaceutical companies to form additional alliances.

We have a significant commercial presence in Spain, where we manufacture and market more than 100 pharmaceutical products, representing various dosage strengths and product formulations of more than 30 chemical entities. Our product line consists of generic and branded products within four primary therapeutic areas: cardiovascular, gastrointestinal, infectious and neurological diseases. Additionally, we have a strategic alliance with Teva Pharmaceutical Industries Ltd. granting us the right to register and market in Spain more than 75 of Teva's pharmaceutical products through our sales force of approximately 150 full-time personnel located in major cities throughout Spain.

INDUSTRY OVERVIEW

Drug Delivery Industry

Drug delivery companies develop technologies to improve the administration of therapeutic compounds. These technologies are designed to enhance safety, efficacy, ease-of-use and patient compliance with prescribed therapy. Drug delivery technologies provide opportunities for pharmaceutical and biotechnology companies to extend their drug franchises as well as develop new and innovative products. The worldwide market for drug delivery systems was estimated to be $35 billion in 2000 and is projected to increase to $75 billion by 2005.

The vast majority of the drugs currently on the market are taken orally or are administered by injection. Oral drug delivery methods, while simple to use, typically subject drugs to first-pass metabolism in the body, which results in drug degradation in the stomach and further neutralization in the liver before reaching the bloodstream. In order to achieve efficacy, higher drug dosages are often used, with increased risks of side effects. The injection of pharmaceuticals, while avoiding first-pass metabolism in the body, also has major limitations, including pain, which can lead to decreased patient acceptance and compliance with prescribed therapy. A decline in patient compliance can increase the risk of medical complications and lead to higher healthcare costs. Also, the costs of injectable drugs typically are higher as a result of the additional costs associated with medical personnel to administer the injections and the costs associated with the purchase and disposal of syringes.

Pharmaceutical and biotechnology companies look to drug delivery enhancements as a way of gaining a competitive advantage. Alternative drug delivery technologies, which avoid first-pass metabolism

In July 2000, we entered into a strategic alliance with Teva, a world leader in generic pharmaceutical products, pursuant to which we were granted a royalty-free non-exclusive license to register and sell more than 75 finished pharmaceutical products representing more than 25 different chemical entities. Under this license agreement, we will register each product with Spain's Ministry of Health.

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RPODUCTS IN DEVELOPMENT

<TABLE>
<CAPTION>

Product Candidate	Technology	Used to Treat
<S>	<C>	<C>
Topical testosterone gel	CPE-215	Hypogonadism
Improved acetaminophen	Solubility Enhancement	Pain relief
Antifungal nail lacquer	CPE-215	Onychomycosis
Androgenic steroid therapy	CPE-215	Chronic Fatigue Syndrome; Fibromyalgia
Intranasal insulin	CPE-215	Diabetes
Intranasal pain management	CPE-215	Pain relief
Topical hormonal therapy	CPE-215	Osteoporosis; Erectile Dysfunction

</TABLE>

Topical Testosterone Gel

Testosterone replacement therapy is used to treat men whose bodies produce insufficient amounts of testosterone (Hypogonadism), which can be a natural result of aging. Symptoms associated with low testosterone levels in men include depression, decreased libido, erectile dysfunction, muscular atrophy, loss of energy, mood alterations, increased body fat and reduced bone density. Currently marketed hormone replacement therapies involve delivery of hormones by injections, through transdermal patches and by gels. Injection therapy has major limitations, including pain, which can lead to decreased patient acceptance and compliance with prescribed therapy. Although patches have been able to alleviate many of the gastrointestinal side effects associated with oral delivery of hormones, patches, even in their smallest form, are often conspicuous and typically result in skin irritation or inaccurate dosing should the patch fall off. The transdermal delivery of hormones through gels, creams and lotions provides commercially attractive and efficacious alternatives to current methods of delivery. In 1999, the worldwide market for testosterone products approached $150 million. As more baby-boomers enter middle age and more attention is focused on male hormonal deficiencies, the testosterone replacement market is expected to reach $1 billion by 2005.

In May 2000, we entered into a research services agreement with Auxilium to develop and test various pharmaceutical compositions of topical testosterone using our CPE-215 technology. A license of our technology to Auxilium became effective in September 2000. Phase III clinical trials performed by Auxilium for approval in the U.S. have been completed. Under the license, we granted to Auxilium a sole and exclusive, royalty-based license worldwide to develop, market and sell a topical testosterone product using our CPE-215 technology.

Improved Acetaminophen

We have developed and patented improved oral formulations of acetaminophen, the active ingredient in such products as McNeil Consumer Healthcare's Tylenol(R) line of products commonly used for controlling pain, fever and inflammation. Our improved oral formulations of acetaminophen make it highly dispersible, rapidly soluble in water, better tasting and faster in reaching peak blood levels. These characteristics give our oral formulations superior properties over other currently marketed products, which do not dissolve easily in water and may cause bitter taste and flatulence. These improvements are particularly useful for treating children, the elderly, and those who have difficulty swallowing pills. Clinical studies in Europe documenting the product's improved dissolution and absorption were completed in 2001. We currently are conducting bioequivalency studies, which compare the rate and extent of absorption and levels of concentration in the blood stream of our improved oral formulations needed to produce a therapeutic effect, with other formulations of acetaminophen that previously have been approved by the FDA. We also are in preliminary discussions with potential collaborators in Europe, Asia and the United States to license and market this product.

Antifungal Nail Lacquer

We have developed a new topical nail lacquer for treating fingernail and toenail fungal infections (Onychomycosis). We believe that our product is an improvement over oral therapies, which can cause liver damage, and other topical treatments that typically have low levels of efficacy. We currently are conducting Phase I/II clinical trials for the treatment of nail fungal infections in the hands and feet at the University of Alabama at Birmingham. According to the National Onychomycosis Society, nail fungus affects almost 30 million people, primarily between the ages of 40 and 65. Patients electing to take oral therapy must undergo blood monitoring during the course of treatment to monitor for liver damage. The cost of oral therapy is in excess of $500 for a twelve-week treatment regimen, not including physician costs or other periodic monitoring costs.

Androgenic Steroid Therapy

We are developing a topical therapy utilizing androgenic steroids, which may incorporate our CPE-215 technology, for the treatment of Chronic Fatigue Syndrome and Fibromyalgia. The manifestations of Chronic Fatigue Syndrome are continuous exhaustion, muscle pain, cognitive disorientation and various other physical or psychological symptoms. Chronic Fatigue Syndrome has not received a high degree of publicity since it is often improperly diagnosed and lacks proven therapies. Chronic Fatigue Syndrome is recognized by the National Institutes of Health, the FDA and the Social Security Administration as a serious, disabling affliction. A study by DePaul University estimates that as many as 800,000 people in the U.S. suffer from this condition and that it is approximately three times more common in women than in men.

According to the National Census Bureau and Dartmouth Medical School, Fibromyalgia afflicts six to eight million people. Fibromyalgia primarily affects women between the ages of 40 and 60 with symptoms of muscle pain, fatigue, chronic headache and sleeplessness and has been estimated to strike as many as five percent of peri/postmenopausal women. A preliminary study conducted by Dartmouth scientists indicates that Fibromyalgia patients demonstrated improved muscle function, higher energy levels and restorative sleep in response to androgenic steroid therapy. We have licensed from Dartmouth College their exclusive U.S. patent rights covering the novel use of androgenic steroid therapy for treating Chronic

Fatigue Syndrome and Fibromyalgia. In 2001, a pilot study of this therapy was

initiated in female volunteers at the Dartmouth Medical Center.

Intranasal Insulin

We are developing intranasal formulations of insulin to treat patients suffering from Type I and Type II diabetes. Based on preclinical studies at various universities, we believe our intranasal insulin formulation can achieve higher levels of bioavailability compared to other drug delivery systems currently being developed and of which we are aware. Our product is designed to deliver insulin through a small, discreet metered nasal spray that can be carried in a patient's pocket. We currently are in preclinical development in collaboration with an independent clinical research organization and the University of New Hampshire in preparation for a pilot study.

Diabetes is a metabolic disorder affecting approximately 100 million people worldwide that is projected to affect more than 300 million people worldwide in the next 25 years. The market for insulin treatment of diabetes in the United States exceeds $1.5 billion annually and Frost & Sullivan estimates that the worldwide market exceeds $3 billion. Diabetic patients who must endure frequent injections prefer less invasive methods of administering their medications. Alternative and more desirable methods of delivery would not only improve their quality of life but also would contribute to patient compliance with prescribed therapy.

Intranasal Pain Management

Many people suffer from chronic moderate to severe pain that is related to cancer, back problems and orthopedic injury. These people also may experience intermittent flares of pain that can occur even though a person is taking analgesic medications on a fixed schedule for pain control. A severe flare of pain is called breakthrough pain because the pain breaks through the regular pain medication. About one-half to two-thirds of patients with chronic cancer-related pain also experience episodes of breakthrough cancer pain. Generally, breakthrough pain occurs without prior onset symptoms and may last anywhere from seconds to minutes or hours. The U.S. prescription market for the treatment of moderate to severe pain, including breakthrough pain, is approximately $2 billion annually.

We are developing an intranasal pain product using our CPE-215 technology with a chemical agent that is widely used for the relief of acute and chronic moderate to severe pain and that commonly is prescribed for pain associated with cancer. Orally delivered pain products may not provide rapid relief and typically demonstrate considerable patient-to-patient variability in absorption. Injectable formulations of pain products provide rapid and effective pain relief, but administration often requires professional assistance or hospitalization. Our intranasal pain product is in preclinical development for the treatment of chronic pain and acute episodes of chronic pain. We believe our intranasal pain product would provide significant medical benefits over oral and injectable formulations as it combines patient convenience and ease of use with the rapid onset of pain relief and the same potency as injectable delivery routes.

We have signed a research agreement with Auxilium pursuant to which we will develop and test the intranasal delivery of a pain management chemical agent using our CPE-215 technology. As part of our strategic alliance with Auxilium, upon Auxilium's acceptance of our preclinical studies, we will grant to them a worldwide license to develop, market and sell the products using our CPE-215 technology.

Topical Hormonal Therapy

Osteoporosis is a disease characterized by low bone mass and structural

deterioration of bone tissue, leading to bone fragility and increased susceptibility to fractures of the hip, spine and wrist. According to the National Osteoporosis Foundation, two million American men have Osteoporosis, and another three million are at risk for this disease. We believe that our topical hormonal therapies, incorporating our CPE-215 technology, have the potential to effectively treat Osteoporosis in men, without the gastrointestinal side effects of the leading oral treatments.

Erectile Dysfunction is defined as the inability to achieve and/or maintain an erection adequate for satisfactory sexual function. Approximately 30 million men in the U.S. and 150 million men worldwide suffer from Erectile Dysfunction. The condition is correlated with increasing age, cardiovascular disease, hypertension, diabetes, hyperlipidemia and smoking. The leading treatments include oral preparations, which have been associated with a slow onset of action and drug interactions, as well as injections, which can cause pain when administered. We believe that our topical hormonal therapies, incorporating our CPE-215 technology, have the potential to effectively treat Erectile Dysfunction, without the side effects of the leading treatments.

Our topical hormonal therapy incorporates the use of metabolic steroids that regulate most of the hormonal action in adult males. Hormone replacement therapies using these metabolic steroids, including testosterone and dihydrotestosterone, may have significant benefits in treating a number of medical afflictions in men, including Osteoporosis and sexual dysfunction. We have signed a research agreement with Auxilium pursuant to which we will provide various topical formulations of the hormones incorporating our CPE-215 technology. Auxilium is evaluating our formulations and plans to perform appropriate preclinical studies. As part of our strategic alliance with Auxilium, upon Auxilium's acceptance of preclinical studies, we will grant to them a worldwide license to develop, market and sell topical hormonal therapies containing our CPE-215 technology to treat Osteoporosis in men and Erectile Dysfunction.

STRATEGIC PARTNERS

Pfizer

In October 2001, we entered into a research collaboration with Pfizer in which we were granted a non-exclusive worldwide royalty-free license to use Pfizer's compounds and technology to assess the performance of our CPE-215 technology with Pfizer's compounds. As part of the agreement, we granted to Pfizer the non-exclusive right to test the ability of our CPE-215 technology to enhance delivery of certain compounds proprietary to Pfizer. Pfizer is providing the funding necessary to conduct these studies using our CPE-215 technology and has agreed to provide additional funding for costs of further studies that are approved by a joint working committee consisting of designees of Pfizer and us. Pfizer has agreed to inform us if, following completion of the research, it is interested in further development of the formulations. Pfizer would have to enter into a separate license agreement with us with respect to the manufacture, use, sale, offer for sale and import of the products using our CPE-215 technology before it could begin to distribute, market and sell these products.

<PAGE>

Auxilium

In May 2000, we entered into a research agreement with Auxilium to develop and test the application of our CPE-215 technology with respect to the transdermal delivery of testosterone. Auxilium is an emerging therapeutic pharmaceutical company focused on diseases related to aging. In September 2000, a license to Auxilium of our CPE-215 technology became effective for a topical testosterone product. Phase III clinical trials performed by Auxilium for approval in the U.S. have been completed. In May 2001 we entered into research agreements with Auxilium to develop and test our CPE-215 technology with respect

to delivery of a pain management compound and a topical hormonal therapy. Preclinical studies currently are underway regarding the application of our CPE-215 technology to a topical hormone therapy.

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As part of our collaboration with Auxilium, we also entered into a license agreement whereby we granted to Auxilium an exclusive royalty-based worldwide license, to develop, market and sell topical testosterone gel containing our CPE-215 technology. This license also provides us with an opportunity to fulfill Auxilium's manufacturing requirements for the sale of the products in the European market. Under the license agreement we would receive payments based upon Auxilium's completion of certain milestones plus royalties based on net sales in territories outside of Spain and we would pay royalties to Auxilium based on our net sales in Spain. Upon successful completion of preclinical studies for the intranasal pain management and topical hormone products, similar licenses would become effective.

Teva

In July 2000, we entered into a strategic alliance with Teva, a world leader in generic pharmaceutical products, in which we were granted a royalty-free non-exclusive license to register and sell more than 75 finished pharmaceutical products representing more than 25 different chemical entities. We are obligated under this license agreement to submit a registration file for each product to the relevant regulatory authorities in Spain in order to receive marketing authorizations in our name for that product. The marketing authorizations provide us with the requisite approvals, licenses and permits from the regulatory authorities to import, distribute, market and sell the products in Spain. In connection with this strategic alliance, Teva also entered into a supply agreement with us pursuant to which it would manufacture the products and supply them to us for marketing and sale in Spain. Our obligation to purchase the products from Teva is non-exclusive, allowing us to purchase any of the products from sources other than Teva if we can show that Teva's prices for the products exceed the current price from other qualified sources and if Teva has not exercised its right to match the lower price.

Under a rights agreement entered into with Teva in July 2000, we granted Teva a right of first refusal to purchase Laboratorios Davur in the event that we decide to sell Laboratorios Davur or Laboratorios Belmac. We also granted Teva the right to bid for Laboratorios Belmac in the event we intend to sell Laboratorios Belmac.

OUR PROPRIETARY DRUG TECHNOLOGIES

We believe that there are numerous opportunities to enter into additional collaborations with pharmaceutical and biotechnology companies and expand our product lines using our proprietary drug technologies.

CPE-215 Permeation Enhancement Platform Technology

Our permeation enhancement technology consists of a series of related chemical compounds that enhance the absorption of a wide variety of products across various biological membranes. Our primary compound and the foundation for our drug delivery platform technology is CPE-215 (cyclopentadecanolide). CPE-215, when combined with certain drugs, has been shown to significantly enhance the amount and rate of absorption of those drugs through various biological membranes. By controlling the amount of CPE-215 that is combined with certain drugs, we have the ability to affect the quantity and rate at which the drug is absorbed through biological membranes. We believe that our CPE-215 technology is superior to certain other non-injection and non-oral drug delivery systems based on the following characteristics:

- broad applicability - works with a wide range of pharmaceutical

compounds, including water and oil soluble and insoluble compounds as well as high and low molecular weight compounds, including peptides and proteins;

- format independence - can be formulated into creams, ointments, gels, solutions, lotions and patches;

B421

- biological membrane independence - works across the biological membranes of the skin, mouth, nose and eye; and

- well tolerated - no reported cases of irritation or toxicity.

CPE-215 has a long history of safe use in humans as a food additive and fragrance. In addition, our preclinical testing to date on CPE-215 as a drug delivery enhancement has further indicated its safety. We believe that this past experience with CPE-215 may result in reduced preclinical development activities required for new product formulations of previously approved pharmaceutical compounds.

Solubility Enhancement Technology

Our solubility enhancement technology involves patent pending chemical and manufacturing procedures that enhance solubility without changing the compound's therapeutic properties. Although this technology can be applied to other chemical entities, to date we have incorporated this technology only in acetaminophen compounds, which are known to have problems of insolubility and undesirable taste. Based upon clinical studies completed in the year 2001, we believe that our technology enables us to develop and deliver dosages of acetaminophen that make it highly dispersible, rapidly soluble in water, better tasting and faster in reaching peak blood levels to deliver pain relief. The use of our technology to increase solubility lessens undesirable side effects, such as flatulence and the bitter taste of pills, which commonly are associated with acetaminophen and many other oral medications.

Improved Oral Formulation Technologies

Our oral formulation technologies involve the application of a new vacuum dry and desiccation manufacturing process as well as specialized equipment, each of which plays a role in producing pharmaceutical products that are more stable and pure, while reducing manufacturing time and costs. We have developed this technology to create new methods for manufacturing products such as omeprazole, lansoprazole and other similar products that are stability sensitive to humidity and temperature. We filed

four new patents in 2000 and 2001 relating to these processes and equipment. The patents claim as innovative the manufacturing process that renders these products more stable, while protecting active substances from gastric degradation utilizing microgranulation and microencapsulation techniques. These patent pending technologies can contribute to our ability to compete against other companies whose manufacturing processes are more costly and time consuming.

Hydrogel Technology

Our hydrogel technology involves a patented synthetic material, which produces a water soluble drug release system capable of being formulated for immediate onset or sustained release over a 24 hour period. The hydrogel technology is capable of adhering to the mucous membranes of the vagina for extended periods of time without typical discharge, improving the treatment of conditions such as yeast and fungal infections or conditions requiring moisturizers or antibiotics. We seek to license this technology to other pharmaceutical companies for co-development and marketing of potential applications of this technology.

PRODUCT SALES AND MARKETING IN SPAIN

In Europe, primarily Spain, we manufacture and market more than 100 pharmaceutical products, representing various dosage strengths and product formulations of more than 30 chemical entities. Our product lines consist of generic and branded products within four primary therapeutic categories: cardiovascular, gastrointestinal, infectious and neurological diseases. Our generic and branded products are marketed to physicians and pharmacists by our two separate sales and marketing organizations, Laboratorios Davur and Laboratorios Belmac. To a lesser extent, we also market over-the-counter products through Laboratorios Belmac. There are approximately 90,000 physicians and 20,000 pharmacies in Spain. Revenues from products whose active ingredient is omeprazole accounted for approximately 56% of our net sales in 2001.

We continuously review and modify our product portfolio. We add to our portfolio to respond to increasing market demand for generic and branded products in Spain and we divest from our portfolio products that we consider to be redundant or that have become non-strategic. We export a small portion of the pharmaceuticals manufactured by Laboratorios Belmac outside Spain through local distributors and brokers, particularly in Eastern Europe, Northern Africa, Central and South America.

Generic Pharmaceuticals

Our generic product line consists of 39 pharmaceutical products representing various dosage strengths and product formulations of ten chemical entities. We entered the generic pharmaceutical market in Spain in September 2000. Laboratorios Davur, our generic sales and marketing organization, markets generic pharmaceutical products to physicians and pharmacists through a sales force of approximately 60 full-time sales personnel located in major cities throughout Spain. In 2001, generic pharmaceuticals accounted for approximately 10% of our total product sales. We also supplement our sales and marketing efforts for generic products through advertising in trade publications.

We believe we can grow by providing to our generic products sales force a more extensive line of products to market to physician and pharmacy clients. To strengthen our entry into the generic market, in July 2000, we entered into a strategic alliance with Teva, one of the world's leaders in generic

pharmaceuticals. Under this alliance, we have licensed from Teva the right to register and market in Spain more than 75 of Teva's pharmaceutical products, representing more than 25 different chemical entities. Pursuant to the arrangement, Teva will supply the pharmaceutical products to us and we will register and, upon regulatory approval, market the products in Spain.

The following are descriptions of our generic products that contribute significantly to our sales and gross profits:

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Our Generic Product Name	Active Ingredient	Sold by Others as
<S>	<C>	<C>
Amoxicilina Davur	amoxicillin trihydrate	Amoxil(R) (GlaxoSmithKline)

Ciprofloxacino Davur	ciprofloxacin hydrochloride	Cipro(R) (Bayer)
Enalapril Davur	enalapril maleate	Vasotec(R) (Merck)
Fluoxetina Davur	fluoxetine hydrochloride	Prozac(R) (Eli Lilly)
Omeprazol Davur	omeprazole	Prilosec(R) (AstraZeneca)
Simvastatina Davur	simvastatin	Zocor(R) (Merck)

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Branded Pharmaceuticals

Our branded product line consists of 62 pharmaceutical products representing various dosage strengths and product formulations of 22 chemical entities. Sales of branded pharmaceuticals accounted for 77% of our product sales in 2000 and 47% in 2001. We market our branded and, to a lesser extent, certain of our generic and over-the-counter products through our Laboratorios Belmac subsidiary, which has approximately 90 full-time sales personnel located in major cities throughout Spain. We supplement our sales and marketing efforts for branded products through advertising in trade publications.

The following are descriptions of the branded products that contribute significantly to our sales and gross profits:

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Our Branded Product Name	Active Ingredient	Sold by Others as
<S>	<C>	<C>
Amoxicilina Belmac(R)	amoxicillin trihydrate	Amoxil(R) (GlaxoSmithKline)
Belmazol(R)	omeprazole	Prilosec(R) (AstraZeneca)
Cimascal D Forte(R)	calcium carbonate and vitamin D3	Calcite-D(R) (Riva)
Codeisan(R)	codeine	Tricodein(R) (Solco)
Simvacol(R)	simvastatin	Zocor(R) (Merck)
Enalapril Belmac(R)	enalapril maleate	Vasotec(R) (Merck)
Mio Relax(R)	carisoprodol	Soma(R) (MedPointe)
Pentoxifilina(R)	pentoxifylline	Trental(R)

Senioral(TM)	oxymetazoline and chlorpheniramine	Denoral(R) (Aventis) (Aventis)

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INTELLECTUAL PROPERTY

We actively seek to protect our products and proprietary information by means of U.S. and foreign patents, trademarks and contractual arrangements. Our success will depend in part on our ability to obtain and enforce patents on our products, processes and technologies to preserve our trade secrets and other proprietary information and to avoid infringing on the patents or proprietary rights of others. Our CPE-215 technology is covered by our U.S. patent and 11 foreign patents, including those in Japan, Korea and most major European countries. We also have three U.S. and four foreign patents pending regarding our CPE-215 technology. The patents for our CPE-215 technology expire in the U.S. in 2008 and in foreign countries between 2006 and 2014. We have one international patent application and one foreign patent application pending regarding our antifungal nail lacquer product. We also have two issued U.S. patents regarding our hydrogel technology that expire in 2008. In addition, we have one U.S. patent pending for an insulin composition. We licensed from Dartmouth College the exclusive rights to a patent covering the novel use of androgen therapy for treating Fibromyalgia and Chronic Fatigue Syndrome. In 2000 and 2001, we filed four new patents in Europe for improved oral formulations of pharmaceutical products, including omeprazole and lansoprazole.

We own approximately 50 trademarks for pharmaceutical products in Spain. In addition, we also rely on unpatented proprietary technologies in the development and commercialization of our products. We also depend upon the unpatentable skills, knowledge and experience of our scientific and technical personnel, as well as those of our advisors, consultants and other contractors. To help protect our proprietary know-how that is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require

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employees, consultants and advisors to enter into agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions that arise from their activities for us. Additionally, these confidentiality agreements require that our employees, consultants and advisors do not bring to us, or use without proper authorization, any third party's proprietary technology.

RESEARCH AND DEVELOPMENT

Our research and product development efforts are focused on developing new product applications of our drug delivery and drug formulation technologies. We currently have ten scientists and technicians working on research and product development. For the years ended December 31, 1999, 2000 and 2001, our research and product development expenditures were $685,000, $1,102,000 and $2,084,000, respectively.

MANUFACTURING

Our 64,000 square-foot manufacturing facility is located in Zaragoza, pain. Our manufacturing facility complies with European Good Manufacturing Practices and is capable of producing tablets, capsules, suppositories, creams, ointments, lotions, liquids and sachets, as well as microgranulated andmicroencapsulated products. The facility also includes analytical chemistry,

quality control, quality assurance and formulation research laboratories.

Since we currently utilize less than 100% of our existing capacity to manufacture our own products, we have engaged in contract manufacturing of pharmaceuticals owned by other companies such as Antibioticos S.A., Laboratorios Cantabria S.A., and Shire Iberica S.A. We believe contract manufacturing provides a stable, recurring source of cash flow, a means of absorbing overhead costs, and experience in manufacturing a broad line of formulations that is advantageous to us in pursuing and integrating acquired products. Although the volume of our contract manufacturing continues to increase, contract manufacturing as a percentage of consolidated net sales declined from approximately 50% in 1994 to approximately 18% in 2001. We attribute this decline to the growth in sales of our own branded and generic pharmaceutical products over the period. We expect that contract manufacturing activities as a percentage of our overall sales will continue to decrease in the future.

We have fully integrated manufacturing support systems including quality assurance, quality control, regulatory compliance and inventory control. These support systems enable us to maintain high standards of quality for our products and deliver reliable products and services to our customers on a timely basis. We require a supply of quality raw materials and packaging materials to manufacture and package drug products. Historically we have not had difficulty obtaining raw materials and packaging materials from suppliers. Currently, we rely on approximately 70 suppliers to deliver our required raw materials and packaging materials. We have no reason to believe that we will be unable to procure adequate supplies of raw materials and packaging materials on a timely basis. Union Quimico Farmaceutica, S.A. is our sole supplier of omeprazole. Revenues from products whose active ingredient is omeprazole accounted for approximately 56% of our net sales in 2001. We believe that alternative sources of omeprazole are available and we will obtain required governmental approval to source from them, if necessary.

COMPETITION

All of our current and future products face strong competition both from new and existing drugs and drug delivery technologies. This competition potentially includes national and multi-national pharmaceutical and healthcare companies of all sizes. Many of these other pharmaceutical and healthcare companies have far greater financial resources, technical staffs, research and development, and manufacturing and marketing capabilities. We believe that owning our own development, manufacturing and marketing facilities in Spain allows us to effectively compete with other pharmaceutical companies in this market. Our access to these resources enables us to reduce costs otherwise associated with contracting for the development, manufacture or marketing of our products by other companies. These reduced costs allow us to sell our products at competitive prices while maintaining attractive margins.

We compete with both large multinational companies and national Spanish companies, which produce most of the same products that we manufacture. In Spain, our principal competitors include companies such as Ratiopharm International GmbH, Merck Sharp & Dohme de Espana, S.A. and Almirall Prodes Farma.

CUSTOMERS

In Spain, our sales representatives from Laboratorios Belmac and Laboratories Davur actively promote our products to physicians and retail pharmacists. We sell our products directly to pharmaceutical distributors and indirectly to customers who purchase our products from distributors. The wholesale distributor network for pharmaceutical products in Europe and more specifically in Spain, in recent years has been subject to increasing consolidation, which has increased and we expect will continue to increase our, and other industry participants', customer concentration.

In 2001 and 2000, Cofares was our only customer accounting for more than ten percent of our consolidated net sales of approximately 15% and 14%, respectively. In 1999, Cofares and Antibioticos Farma, each of whose purchases accounted for approximately 13% of consolidated net sales, were the only customers which accounted for more than ten percent of consolidated net sales.

B426

REGULATION

Numerous governmental authorities in the U.S. and other countries extensively regulate the activities of pharmaceutical manufacturers. If we fail to comply with the applicable requirements of governmental authorities, we may be subject to administrative or judicial sanctions such as warning letters, fines, injunctions, product seizures or recalls, total or partial suspension of production, or refusal by governmental authorities to approve pending marketing approval applications or supplements to approved applications, as well as criminal prosecution.

United States

Prior to marketing a pharmaceutical product in the U.S., the product must be approved by the FDA. For new compounds, the regulatory approval process begins with preclinical laboratory and animal testing. Upon completion, an Investigational New Drug Application is submitted to the FDA, which must become effective before human clinical trials may be commenced. Sometimes, to minimize costs, we have chosen to

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conduct pilot studies. The data they produce can permit us to move directly into Phase II or III studies with the FDA.

Following completion of laboratory animal testing, human clinical trials typically are conducted in three sequential phases that may overlap.

- Phase I - involves the initial introduction of the pharmaceutical into healthy human volunteers, the emphasis is on testing for safety (adverse effects), dosage tolerance, metabolism, excretion and clinical pharmacology.

- Phase II - involves studies in a limited patient population to determine the efficacy of the pharmaceutical for specific targeted indications, to determine dosage tolerance and optimal dosage and to identify possible adverse side effects and safety risks.

- Phase III - involves trials undertaken to evaluate clinical efficacy once a compound is found to be effective and to have an acceptable safety profile in Phase II evaluations, and to further test for safety within an expanded patient population at multiple clinical study sites.

The FDA reviews both the clinical plans and the trial results and may discontinue the trials at any time if there are significant safety issues. The results of preclinical and clinical trials are submitted to the FDA in the form of a New Drug Application for marketing approval. The approval process is affected by a number of factors, including the severity of the disease, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. Additional animal studies or clinical trials may be requested during the FDA review process and may delay marketing approval. After FDA approval for the initial indications, further clinical trials would be necessary to gain approval for the use of the product for any additional indications. The FDA may also require post-marketing testing to monitor for adverse effects, which can involve significant expense. Our products under

development and future products to be developed must go through the approval process delineated above prior to gaining approval by the FDA for commercialization.

FDA approval is required for the marketing of generic equivalents or new dosage forms of an existing drug. An Abbreviated New Drug Application is required to be submitted to the FDA for approval. When processing an ANDA, the FDA waives the requirement of conducting complete clinical studies, although it normally requires bioavailability and/or bioequivalence studies. Bioavailability indicates the rate and extent of absorption and levels of concentration of a drug product in the blood stream. Bioequivalence compares the bioavailability of one drug product with another, and when established, indicates that the rate of absorption and levels of concentration of a generic drug in the body closely approximate those of the previously approved drug. An ANDA may be submitted for a drug on the basis that it is the equivalent to a previously approved drug.

In addition to obtaining FDA approval for each product, each manufacturer of drugs must be registered with the FDA. Domestic manufacturing establishments are subject to biennial inspections by the FDA and must comply with current Good Manufacturing Practices for drugs. To supply products for use in the U.S., foreign manufacturing establishments must comply with GMPs and are subject to periodic inspection by the FDA or by regulatory authorities in such countries under reciprocal agreements with the FDA.

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Spain and Europe

As a pharmaceutical manufacturer in Spain, which is a member of the European Union, we are subject to the regulations enacted by the European Union. Prior to Spain's entry into the European Union in 1986, the pharmaceutical regulations in Spain were less stringent. Since that time, we, along with all Spanish pharmaceutical companies, must obtain manufacturing, marketing and pricing authorizations to commercialize pharmaceutical products in Spain. Pharmaceutical manufacturers in Spain must obtain from the Spanish Ministry of Health a general permit to operate a pharmaceutical business certifying that its facilities comply with European Good Manufacturing Practices. For marketing authorization of new products, the development process in Spain is comprised of three clinical phases for branded drugs and bioequivalent studies for generic drugs as in the U.S. to assure their safety and efficacy. A dossier must be prepared on each pharmaceutical product and, upon approval of the product by the Spanish Ministry of Health, it may be marketed in Spain. Finally, the Spanish Ministry of Health sets maximum prices and reimbursement rates for our products.

Trends in Healthcare Regulation

The cost of healthcare continues to be a subject of investigation and action by governmental agencies, legislative bodies and private organizations. In the United States, most states have enacted generic substitution legislation requiring or permitting a dispensing pharmacist to substitute a different manufacturer's version of a drug for the one prescribed. Federal and state governments continue their efforts to reduce costs of subsidized healthcare programs, including restrictions on amounts agencies will reimburse for the use of products. Efforts to reduce healthcare costs are also being made in the private sector. Healthcare providers have responded by instituting various cost reduction and containment measures of their own. It is not possible to predict the extent to which we or the healthcare industry in general might be affected by these changes.

Continuing reviews of the utilization, safety and efficacy of healthcare products and their components are being conducted by industry, government agencies and others. These studies, which employ increasingly sophisticated methods and techniques, can call into question the utilization, safety and efficacy of previously marketed products and in some cases have resulted, and may in the future result, in the discontinuance of such products and give rise

result of their use. We maintain product liability insurance for such potential claims; however, no such claims have ever been asserted against us.

Many countries, directly or indirectly through reimbursement limitations, control the selling price of certain healthcare products. In addition, the prices for all prescription products in Spain are determined by the Spanish Ministry of Health. In Western Europe, efforts are under way by the European Union to harmonize technical standards for many products, including drugs, to make more uniform the requirements for marketing approval from the various regulatory agencies.

Other Regulations

We believe that we comply with environmental laws that apply to us and we do not anticipate that compliance will have a material effect on our financial condition.

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EMPLOYEES

We employ approximately 265 people, nine of whom are employed in the U.S. and 256 in Spain, as of December 31, 2001. Approximately 67 of these employees principally are engaged in manufacturing activities, 152 in sales and marketing, ten in product development and 36 in management and administration. In general, we consider our relations with our employees to be good.

RISK FACTORS

You should carefully consider the following risk factors and warnings. The risks described below are not the only risks we face. Additional risks that we do not yet know of or that we currently think are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks actually occurs, our business, financial condition, or results of operations could be materially adversely affected. In such case, the trading price of our common stock could decline.

OUR GROWTH DEPENDS ON IDENTIFYING DRUGS SUITABLE FOR OUR DRUG DELIVERY TECHNOLOGIES.

Bentley's growth depends on the identification of pharmaceutical products that are suitable for delivery using our technologies. We intend to expend significant resources and efforts toward identifying and commercializing these pharmaceutical products. Identifying suitable products is a lengthy and complex process that may not succeed. Even if identified, products may not be available to us or we may otherwise be unable to enter into licenses or other agreements for their use. In our efforts to identify suitable products, we compete with other pharmaceutical delivery companies with greater research and development, financial, marketing and sales resources. If we do not effectively identify drugs to be used with our technologies, improve the delivery of drugs with our technologies and bring the improved drugs to commercial success, then we will not be able to continue our growth and we will be adversely affected.

OUR GROWTH ALSO DEPENDS ON EXPANDING OUR GENERIC AND BRANDED DRUG OPERATIONS.

We intend to expend significant resources and efforts toward identifying and commercializing products and technologies to expand our generic and branded drug operations in Spain. Identifying and pursuing these opportunities involves significant time and expense and we may not succeed. Even if identified, these products and technologies may not be commercially successful. Once identified, products to be manufactured and/or marketed by us under generic or branded names are subject to successful negotiation of acceptable economic and legal terms,

and successful progress of the product through commercialization, as to which we cannot assure you. In these efforts, we compete with other pharmaceutical companies having generic and branded drug operations with greater financial, marketing and sales resources. If we do not effectively identify generic and branded drug products and technologies and bring them to commercial success hen we will not be able to continue our growth and we will be adversely affected.

B429

PRODUCTS USING OUR TECHNOLOGIES ARE IN VARIOUS STAGES OF DEVELOPMENT AND MAY NOT ACHIEVE COMMERCIAL SUCCESS.

Independently as well as in conjunction with strategic partners, we are investigating the use of our technologies with respect to a variety of pharmaceutical compounds and products that are in various stages

of development. We are unable to predict whether any of these products will receive regulatory clearances or be successfully developed, manufactured or commercialized. Further, due to the extended testing and regulatory review process required before marketing clearance can be obtained, the time periods before commercialization of any of these products are long and uncertain. Risks during development include the possibility that:

- any or all of the proposed products will be found to be ineffective;
- the proposed products will have adverse side effects or will otherwise fail to receive necessary regulatory clearances;
- the proposed products may be effective but uneconomical to market; or
- other pharmaceutical companies may market equivalent or superior products.

WE WILL RELY ON STRATEGIC PARTNERS TO COMMERCIALIZE PRODUCTS THAT USE OUR DRUG DELIVERY TECHNOLOGIES.

We require substantial funds and other resources to complete development of products deliverable using our technologies and anticipate forming alliances with others to develop, manufacture, market and sell our products in the United States and other countries. We continue to pursue strategic partners for these purposes. We may not be successful in finding strategic partners or in otherwise obtaining financing, in which case the development of our products would be delayed or curtailed.

We must enter into agreements with strategic partners to conduct clinical trials, manufacturing, marketing and sales necessary to commercialize product candidates. In addition, our ability to apply our drug delivery technologies to any proprietary drugs will depend on our ability to establish and maintain strategic partnerships or other collaborative arrangements with the holders of proprietary rights to such drugs. Arrangements with strategic partners may be established through a single comprehensive agreement or may evolve over time through a series of discrete agreements, such as letters of intent, research agreements and license agreements. We cannot assure you that we will be able to establish such strategic partnerships or collaborative arrangements on favorable terms or at all or that any agreement entered into with a strategic partner will lead to further agreements or ultimately result in commercialization of a product.

In collaborative arrangements, we will depend on the efforts of our strategic partners and will have limited participation in the development, manufacture, marketing and commercialization of the products subject to the collaboration. We cannot assure you that these strategic partnerships or collaborative arrangements will be successful, nor can we assure you that